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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,191	01/03/2002	Walter Schubert	HSS-022XX	6276

207 7590 07/28/2005

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,191	SCHUBERT, WALTER	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-15,17-21,23,24 and 27-30* is/are pending in the application.

4a) Of the above claim(s) *1,2,4-7,9-15,17-20 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23,24 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.o.o

DETAILED ACTION

Election/Restrictions

Newly amended claims 1, 2, 4, 5, 6, 7, and newly submitted claims 27-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the elected invention already examined on merits is drawn to product i.e. aminopeptidase inhibitor for production of medicament and pharmaceutical comprising aminopeptidase inhibitor or utilization of an aminopeptidase inhibitor for production of medicament, i.e. a medicament product (i.e. pharmaceutical) production by utilization of the an aminopeptidase inhibitor. Newly amended claims 1, 2, 4, 5, 6, 7, and newly submitted claims 27-30 are drawn to method of treating disease, which is a different invention for the following reasons.

As stated in the previous Office action mailed on 10/20/2004, PCT Rule 13.2 and 37 C.F.R. 1.475 define "special technical feature" as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The special technical feature of the elected invention is an aminopeptidase inhibitor, which is taught by WO 98/44923, and other prior art of record. Note the art rejection of record and Election/Restrictions Requirement of record.

Since the first claim lacks the special technical feature, the unity between the product and the first method of the product is lacking, thus the restriction between the product and method of using the product is proper. In addition, a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present

drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; (2) A product and a process of use of said product; (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; (4) A process and an apparatus or means specifically designed for carrying out said process; or (5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 2, 4. 5, 6. 7. and 27-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 9-15, and 17-20 are withdrawn for reason of record from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 2, 4-7, 9-15, and 17-21. 23, 24, 27-30 are pending. Claims 21, 23, 24, and 30 are examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification, Withdrawn

The objection of the specification is withdrawn in view of the amendment.

Claim Objections, Withdrawn

The objection of claims 21, 23, and 24 is withdrawn because the amended claims are interpreted as drawn to pharmaceutical comprising an aminopeptidase inhibitor that blocks polarization of an invasive tumor cell. The different proteins recited in the claims are interpreted as describing the protein network, not an inhibitor to the specific protein.

All other objection not repeated here is moot because of either cancellation or being withdrawn of the claims.

Claim Rejections - 35 USC § 101, Withdrawn

The rejection of claims 21, 23, and 24 is withdrawn in view of the amendment.

All other rejection not repeated here is moot because of either cancellation or being withdrawn of the claims.

Claim Rejections - 35 USC § 112

The rejection of claims 21, 23, 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

Claims 21, and 23, 24 **remain rejected,** and the **new claim 30 is also** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are two parts to this rejection.

This **written description rejection** is being maintained because the claimed invention is interpreted as drawn to pharmaceutical comprising genus of CD13 aminopeptidase inhibitors.

Applicant states that the submitted amendment to claims would obviate the rejection of record.

Applicant statement and the amended claims are fully considered but found unpersuasive because the amended claims 21, 23, 24, and 30 still do not recite the complete or partial structure of the claimed inhibitor, nor do the claims provide physical and/or chemical properties, structure/function correlation, methods of making the claimed inhibitor. Only factor present in the claims are the functional characteristics of either at least one aminopeptidase or at least one additional peptidase. A definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lily*, 119 F.3 at 1568, 43 USPQ2d at 1406. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 102, Maintained

Claims 21, 23, and 24 **remain rejected**, and **new claim 30 is newly rejected** under 35 U.S.C. 102(b) as being anticipated by any one of WO 98 44923 (1998, IDS filed on 01/03/2002), Kagechika et al., (1999, Biol. Pharm. Bull., 22(9), 1010-1012, IDS filed on 01/03/2002), Xu et al., (Clin Cancer Res. 1998 Jan;4(1):171-6, IDS filed on 01/03/2002), or Fujii et al., (1996, Biol. Pharm. Bull. 19 (1), 6-10, IDS filed on 01/03/2002).

Claims 21, 23, 24, and 30 are broadly interpreted as drawn to a product and/or composition comprising at least one aminopeptidase inhibitor wherein said at least one aminopeptidase inhibitor is homophtalimide type and/or actinonin and/or bestatin, and/or an antibody to CD13, in particular a monoclonal antibody, against CD13 (note applicant's election), wherein claim 24 has the limitation "an additional inhibitor".

Applicant argues that several claims are amended to recite method, and also argues that the art of record does not teach the amended method claims. However, the claims reciting method of treatment has been withdrawn for reasons given above under the heading ***"Election/Restrictions"*** above.

Applicant argues that the prior art of record does not disclose that an aminopeptidase inhibitor that causes blocking of polarization of an invasive tumor cell by modifying at least one surface protein, thus not teaching each limitation of the claims. These arguments have been fully considered but found unpersuasive for the following reasons. The claims are drawn to product per se, and the products, (i.e. homophtalimide actinonin, bestatin, and/or an antibody to CD13) as recited in the now

withdrawn claim 2. Any one of the references cited above discloses that the same products. Thus, the product of the prior art of record inherently possesses the function of "an aminopeptidase inhibitor that causes blocking of polarization of an invasive tumor cell by modifying at least one surface protein". In other words, homophtalimide actinonin, bestatin, and/or an antibody to CD13 inherently possess the function of blocking of polarization of an invasive tumor cell by modifying at least one surface protein.

As for claim 24, where the additional inhibitor modifying at least one surface protein that is not an aminopeptidase, WO 98 44923 especially at page19 teaches that actinonin, CD13/aminopepdaise-N inhibitor inhibits not only growth CD13 positive cells but also inhibits CD13 negative cells, "suggesting that the effect is not medicated by CD13/APN". Note page 19 lines 19-20. This teaching suggests that an aminopeptase inhibitor could inhibit a protein network that is not an aminpeptidase. In other words, actinonin and other CD13 inhibitor could also inhibit other proteins that are not aminopeptases. Since the specification does not teach that the structural difference between the aminopeptidase inhibitor and "an additional inhibitor modifying at least one surface protein that is not an aminopeptidase", along with teaching of WO 98 44923 about the functional nature of actinonin, it is the Office's position that whether the prior art of record all disclosing more than more inhibitors that inhibits tumor cell growths by modifying CD13 and/or modifying the limitation is broadly interpreted a single structure could function to modify CD13, which is a aminopeptidase, and also to inhibit at least

one surface protein that is not an aminpeptidase. Also note the construction of claims 1, and 4 of the instant specification as originally filed.

The following is the reiteration of the previous Office action.

WO 98 44923 teaches for example at page 2, at least one aminopeptidase inhibitor, wherein said at least one aminopeptidase inhibitor is homophtalimide type and/or actinonin and/or bestatin. The limitation "an additional inhibitor" is anticipated by the art because the art teaches more at least one inhibitor and "an additional inhibitor".

Kagechika et al., (1999, Biol. Pharm. Bull., 22(9), 1010-1012, IDS filed on 01/03/2002) teach at page 1010 the instantly claimed invention, i.e. at least one aminopeptidase inhibitor, wherein said at least one aminopeptidase inhibitor is homophtalimide type and/or actinonin and/or bestatin. The limitation "an additional inhibitor" is anticipated by the art because the art teaches more at least one inhibitor and "an additional inhibitor".

Xu et al., (Clin Cancer Res. 1998 Jan;4(1):171-6, IDS filed on 01/03/2002) teach i.e. at least one aminopeptidase inhibitor, wherein said at least one aminopeptidase inhibitor is homophtalimide type and/or actinonin and/or bestatin. The limitation "an additional inhibitor" is anticipated by the art because the art teaches more at least one inhibitor and "an additional inhibitor". Note the heading "Materials" at page 171, right column.

Fujii et al., (1996, Biol. Pharm. Bull. 19 (1), 6-10, IDS filed on 01/03/2002) also teach at least one aminopeptidase inhibitor, wherein said at least one aminopeptidase inhibitor is homophtalimide type and/or actinonin and/or bestatin. The limitation "an

additional inhibitor" is anticipated by the art because the art teaches more at least one inhibitor and "an additional inhibitor". Note Table 1 at page 7.

Thus, any one of WO 98 44923, Kagechika et al., Xu et al., or Fujii et al., anticipate claims 21, 23, 24, and 30.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D
Examiner
Art Unit 1642

Misook Yu